

SEP 10 1998

K982223

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: CAPIOX® SX Hardshell Reservoir

Classification Name: Cardiopulmonary bypass blood reservoir, defoamer,
cardiotomy suction line filter

Reason for Submission:

Addition of the use of vacuum assisted venous drainage to the intended use of the hardshell reservoir.

Intended Use:

The CAPIOX SX Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The CAPIOX SX Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

The Hardshell Reservoir is also used with vacuum assisted venous return during cardiopulmonary bypass.

Description

CAPIOX® SX hardshell reservoir has a rotatable venous blood inlet port to permit minimizing tubing lengths which could result in lower circuit priming volumes.

The Hardshell reservoir contains a defoamer and a screen filter in the venous blood inlet section. The defoamer resides in the upper part of the reservoir permitting blood to reside in the lower section of the reservoir while not in constant contact with the defoamer. The total capacity of the reservoir is 4,000 mL.

The cardiotomy section of the hardshell reservoir contains a defoamer and a cardiotomy filter to facilitate gas bubble removal and the removal of particulates/emboli from suctioned blood entering the reservoir.

II - Summary and Certification
Summary of Safety and Effectiveness

Substantial Equivalence

The CAPIOX® SX Reservoir is substantially equivalent to the Baxter Bentley HSR4000 (K915573) and Bentley BMR Venous Reservoir (K971455) # as follows:

Intended use: same as described on previous page.

Design

These devices are constructed from a clear plastic casing containing filter and defoamer elements.

Technology and Principles of Operation

Both devices utilize gravity and/or external vacuum (cardiotomy) for blood collection into the reservoir. Air removal is facilitated by defoamers and the tendency of air to rise through liquid. Particulate removal is facilitated by the blood flow pathway through filters contained in the reservoirs. Vacuum can be applied to the reservoirs to increase venous return.

The CAPIOX SX Hardshell Reservoir and the Baxter Bentley HSR4000 and Bentley BMR Venous Reservoir are substantially equivalent in design, technology and principles of operation.

Specifications

Table 1

Item	CAPIOX SX18/25 Reservoir	Bentley HSR Reservoir
Reservoir volume		
Maximum	4,000 mL	4,500 mL
Minimum operating volume	200 mL	300 mL
Blood flow rate during cardiopulmonary bypass	Cardiotomy inlet: 0.5-5LPM Venous flow: 0.5-7 LPM	1-5 LPM 1-7 LPM
Cardiotomy Filtration Efficiency	Greater than 90% efficiency for particles $\geq 20\mu$	80% efficiency for particles $> 20\mu$

The specifications of the CAPIOX SX Hardshell Reservoir and the Baxter Bentley HSR4000 and are substantially equivalent.

In summary, the CAPIOX® SX Reservoir and the Baxter Bentley HSR4000 and Bentley BMR Venous Reservoir are substantially equivalent in intended use, design and materials, technology/principles of operation, specifications and performance. Differences as described above do not raise new issues of safety or effectiveness.

Terumo's statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Additional Safety Information

- Pyrogen Testing
- Sterilization conditions have been validated to provide a Sterility Assurance Level (SAL) of 10^{-6} .
- Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).
- Manufacturing control testing
- Blood contacting materials were tested in accordance with the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, " Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (External communicating devices/Circulating Blood/Limited contact duration).

II - Summary and Certification
Summary of Safety and Effectiveness

Date Prepared June 17, 1998

Prepared by: Sandi Hartka,
Manager Regulatory Affairs

for: Terumo Medical Corporation
2101 Cottontail Lane
Somerset, NJ 08873



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1998

Ms. Sandi Hartka
Manager, Regulatory Affairs
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K982223
CAPIOX® SX Harshell Reservoir
Regulatory Class: II (two)
Product Code: DTN
Dated: June 22, 1998
Received: June 24, 1998

Dear Ms. Hartka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, 'Misbranding by reference to premarket notification' (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory,
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K 982223

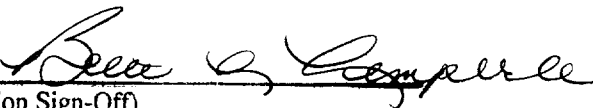
Device Name: CAPIOX® SX Hardshell Reservoir

Indications For Use:

The CAPIOX SX Hardshell Reservoir is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiectomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal.

The Hardshell Reservoir is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement

The Hardshell Reservoir is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 982223

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)